**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| **Z.H. by and through KEVIN HUTCHENS and CHRISTIN HUTCHENS, individually, and as parents and next friends of Z.H.** | ) | **CASE NO.1:14CV176** |
| **Plaintiffs,** | ) | **JUDGE CHRISTOPHER A. BOYKO** |
| **Vs.** | ) | |
| **ABBOTT LABORATORIES, INC. and ABBVIE, INC.** | ) | **ORDER** |
| **Defendant.** | ) | |

**CHRISTOPHER A. BOYKO, J:**

This matter is before the Court on Defendants' Motion to Exclude Certain Testimony from Plaintiffs' Designated Expert Witness Cheryl Blume, Ph.D. (ECF # 89). For the following reasons, the Court grants, in part, and denies, in part, Defendants' Motion.

Dr. Cheryl Blume is a pharmacologist and toxicologist and President of Pharmaceutical Development Group, Inc. (PDG), a consulting firm founded in 1999 and specializing in development and registration activities related to products regulated by the U.S. Food and Drug Administration (FDA). Plaintiffs list Dr. Blume as an expert on drug labels. Defendants seek to exclude Dr. Blume's opinions on the following matters: 1) the Depakote label should have warned that Depakote was more teratogenic than other antiepileptic drugs ("AEDs"); 2) the Depakote label should have included the warning that Depakote should only be used by women

of child-bearing age as a last resort; 3) the Depakote label contained an anti-warning insofar as it compared the teratogenic risk of Depakote as similar to the risks associated with the use of other AEDs; 4) the Depakote label should have contained a warning that one risk of Depakote use was fetal valproate syndrome; and 5) Depakote label should have contained a warning against the risks of poly-therapy. Defendants further seek to exclude all of Dr. Blume's labeling testimony because she fails to propose an alternative warning.

Rule 702 of the Federal Rules of Evidence states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Under Federal Rules of Evidence, a trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, (1993). The objective of *Daubert's* "gatekeeping" function is to ensure the reliability and relevancy of expert testimony. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). The Supreme Court has held this "gatekeeping" obligation applies not only to scientific testimony, but to all expert testimony. *Id*. at 147. Courts are not required to hold a formal hearing on *Daubert* challenges. *See Greenwell v. Boatwright,* 184 F.3d 492, 498 (6th Cir.1999). "[N]o matter how good" experts' "credentials" may be, they are "not permitted to speculate." *Tamraz v. Lincoln Elec. Co.,* 620 F.3d 665, 671 (6th Cir. 2010) quoting *Goebel v. Denver & Rio Grande W. R.R. Co.,* 215 F.3d 1083, 1088 (10th Cir.2000). "The party offering expert testimony bears the burden of establishing the foundational elements

of admissibility by a preponderance of proof." *Jones v. Pramstaller*, 874 F. Supp. 2d 713, 718 (W.D. Mich. 2012) citing *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir.2001). "Nevertheless, Rule 702's requirements are applied liberally, leaving '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [as] the traditional and appropriate means of attacking shaky but admissible evidence.'" *Jones*, 874 F.Supp.2d at 718 quoting *Daubert*, 509 U.S. at 596.

**1) Depakote label should have warned that Depakote was more teratogenic than other AEDs.**

According to Defendants, Dr. Blume's proffered opinions are irrelevant to the facts of this case. Regarding her opinion that the Depakote label should have warned it was more teratogenic than other AEDs, Defendants argue Dr. Foldvary already knew in 2002 that Depakote may present a higher risk of birth defects than other AEDs. Thus, even if the 2002 Depakote label contained such a warning it would not have changed Dr. Foldvary's decision to prescribe it for Christin. In fact, by 2001 Christin had already tried seven other AEDs that either didn't control her symptoms or caused adverse reactions. Therefore, even if Dr. Foldvary had the benefit of the additional warnings on the comparative teratogenicity of Depakote versus other AEDs it would not have mattered since Christin had already tried the other AEDs with no success.

Also, Defendants point out that the only other AED Christin was willing to take in 2001-2002 was Lamictal. Lamictal was a relatively new drug and there was no data demonstrating that Depakote was more teratogenic that Lamictal at that time. Dr. Foldvary testified that Lamictal was not on the market long enough to study its teratogenicity.

Plaintiffs oppose Defendants' Motion, relying on Dr. Foldvary's testimony that at the time she prescribed Depakote to Christin she was unaware that Depakote presented a significantly higher risk of birth defects than other AEDs and had she been aware it may have impacted her prescribing decision and she would have informed Christin of the risks. Christin testified that had she been told of the risks she would not have taken Depakote at that time.

Given Dr. Foldvary's testimony that her decision to prescribe Depakote to Christin may have been impacted if she knew that Depakote presented significantly higher risk of birth defects, the Court finds Dr. Blume's opinion relevant and denies Defendants' Motion. However, depending on Dr. Foldvary's trial testimony, the Court may revisit this issue.

**2) Depakote label should have contained a last resort warning**

Defendants further challenge Dr. Blume's opinion that the Depakote label should have contained a warning that it be used only as a last resort for women of child bearing age. Defendants contend that Christin was put on Depakote only after she tried seven other AEDs and Dr. Foldvary determined surgery was not an option. Thus, any last resort warning is inapplicable to the facts of this case because Christin had tried other AEDs with no success. Even though Dr. Foldvary testified that Depakote was not a last resort for Christin in June 2002 because she could have tried Lamictal, this argument is unavailing because Dr. Foldvary testified it can take a year to switch from Depakote monotherapy to Lamictal monotherapy. If Christin's decision to get pregnant was imminent, there was no time to switch therapies and Dr. Foldvary testified that she told Christin in June of 2002 that if she wanted to get pregnant now she should remain on Depakote. Christin chose not to wait.

Plaintiffs again cite to Dr. Foldvary's testimony in opposition to Defendants' Motion

seeking to exclude as irrelevant Dr. Blume's opinion that the Depakote label should have contained a warning that it be used only as a last resort for women of child-bearing age. Dr. Foldvary and other treating healthcare providers of Christin's testified that Depakote was not a last resort for Christin and that other AEDs could have been prescribed to treat her seizures.

Based on Dr. Foldvary's testimony, Dr. Blume's opinion on the inclusion of a "last resort" warning on the Depakote label is relevant to Dr. Foldvary's knowledge and the impact it would have had on her prescribing decisions. Therefore, Defendants' Motion is denied. However, based on the trial testimony of Dr. Foldvary, the Court may revisit this issue.

**3) Dr. Blume's anti-warning opinion**

Defendants seek to exclude Dr. Blume from testifying that the 2002 Depakote label contained an "anti-warning" when it noted that children exposed to other AEDs also experienced birth defects. Defendants argue that because Dr. Blume is not a medical doctor and never prescribed medication, only Dr. Foldvary can discuss how she interpreted the warning. Defendants further contend that it is absurd to say that a drug with a Black Box warning about birth defects is an anti-warning.

Dr. Blume opines that the medical evidence at the time indicated that Depakote was significantly more teratogenic than other AEDs, therefore, the Depakote label was wrong and Abbott knew or should have known that it conveyed false information.

The Court agrees with Plaintiff that Dr. Blume is qualified to opine on whether the information provided on the Depakote warning label was inaccurate or falsely portrayed Depakote as similarly teratogenic to other AEDs. Dr. Blume is a pharmacologist and toxicologist and directed interactions with the FDA on new drug applications. She has

experience in collecting data on adverse drug events, updating labeling of drugs and in providing information on drugs to healthcare providers and patients. Based on her training and experience she is qualified to opine on the adequacy of the Depakote label. Defendants' challenges go to the weight accorded Dr. Blume's testimony, not its relevance. Therefore, the Motion is denied. However, based on Dr. Foldvary testimony at trial, the Court may revisit this issue.

**4) Depakote label should have warned about fetal valproate syndrome**

Dr. Blume has previously testified in a Depakote trial that the Depakote label should have included a warning that researchers reported that children exposed to Depakote and born with multiple malformations were described as having fetal valproate syndrome. Defendants seek to exclude this testimony as irrelevant because Dr. Foldvary was already aware of the fact as she cited to a medical journal article entitled "The Fetal Valproate Syndrome" in her 2001 book chapter. Thus, the inclusion of such a warning on the Depakote label would not have altered Dr. Foldvary's decision to prescribe Depakote to Christin.

According to Plaintiffs, Defendants improperly speculate on whether such a warning would have altered Dr. Foldvary's decision-making because they never questioned Dr. Foldvary about this issue in her deposition.

Without a basis for knowing the extent of Dr. Foldvary's knowledge of fetal valproate syndrome and what effect, if any, it had on her decision to prescribe Depakote to Christin, the Court cannot conclude Dr. Blume's opinion is irrelevant. Therefore, the Court denies at this time Defendants' motion, subject to revision based on the trial testimony of Dr. Foldvary.

**5) Depakote label should have included a warning on the risks of polytherapy**

Defendants seek to exclude any opinion testimony of Dr. Blume that the Depakote label presented a higher risk of birth defects when taken in combination with other AEDs (polytherapy) than when taken alone (monotherapy) because Christin was not on polytherapy when she conceived Z.H.

Plaintiffs do not oppose Defendants on this issue and the Court grants Defendants unopposed motion to exclude Dr. Blume's testimony.

**6) Dr. Blume's labeling opinions must be excluded because she does not offer a draft of an alternative Depakote label**

According to Defendants, Dr. Blume's labeling testimony is inadmissible because she failed to propose an alternative label, rendering her opinions unreliable under Sixth Circuit law. In *Brown v. The Raymond Corp*. 432 F.3d 640, 648 (6th Cir. 2005) the Sixth Circuit held "failure to propose alternative warnings subject to empirical testing rendered his testimony unreliable and irrevelant to the trier of fact."

Plaintiffs read *Brown* less restrictively, arguing that Ohio law does not impose on a labeling expert the duty to draft an alternative warning. Furthermore, Dr. Blume's Report details the inadequacies of the 2002 Depakote label and provides with sufficient detail what the warning label should have included. Plaintiffs distinguish the cases offered by Defendants, contending that in *Brown,* the Court excluded plaintiff's expert because he never considered what the warning should have said, while Dr. Blume, undeniably qualified as a labeling expert, has studied drug label warnings and includes in her opinions what the label should have warned against.

The Court agrees with Plaintiffs that Dr. Blume has provided sufficient detail on what

the failings of the Depakote label are and what risks it should have warned against based on the medical literature available at the time. This case is distinguishable from *Brown*, where the court excluded the testimony of Brown's expert because he was not found by the court to be an expert in the relevant field, did not prepare an alternative warning, had not thought about what it should have warned against and had no basis on which to opine that additional warnings would likely have prevented the injury, or that the forklift was unreasonably dangerous. Here, Dr. Blume has outlined the basis for her opinions that the Depakote label failed to adequately warn of the risks associated with its use by women of child-bearing age and she specifically outlined what risks it should have warned against. Therefore, the Court denies Defendants' Motion on this issue.

IT IS SO ORDERED.

s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge

Dated: January 5, 2017